Complete Summary

GUIDELINE TITLE

Stereotactic radiosurgery for patients with intractable typical trigeminal neuralgia who have failed medical management.

BIBLIOGRAPHIC SOURCE(S)

IRSA. Stereotactic radiosurgery for patients with intractable typical trigeminal neuralgia who have failed medical management. Harrisburg (PA): IRSA; 2003 Sep. 10 p. (Radiosurgery practice guideline report; no. 1-03). [43 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Trigeminal neuralgia, typical (tic douloureux)

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Neurological Surgery
Neurology
Radiation Oncology

INTENDED USERS

Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To develop an evidenced and consensus-based stereotactic radiosurgery practice guideline for trigeminal neuralgia treatment recommendations to be used by medical and public health professionals following the diagnosis of trigeminal neuralgia

TARGET POPULATION

Men and women with intractable (medically refractory) typical trigeminal neuralgia, often those with concomitant medical co-morbidity or advanced age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Stereotactic radiosurgery dosing schedules:
    - 75 Gy (single fraction to the trigeminal nerve)
    - 80 Gy (central dose targeted to the trigeminal nerve a few millimeters proximal to its entry into the brain stem)
    - 90 Gy (central dose to the trigeminal nerve near the trigeminal ganglion)
2. Follow-up
    - Assess pain relief (3, 6, 12 months)
    - Taper off medications if patient remains pain free
3. Recurrent trigeminal neuralgia
    - Repeat radiosurgery (50 – 60 Gy)

MAJOR OUTCOMES CONSIDERED

- Pain control
- Quality of life
- Neurological outcome

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and PUBMED searches were completed for the years 1966 to September 2003. Search terms included: tic douloureux, trigeminal neuralgia, stereotactic radiosurgery, Gamma Knife®, irradiation, clinical trials, linear accelerator, research design, practice guidelines, and meta-analysis. Bibliographies from recent published reviews were reviewed and relevant articles were retrieved.

NUMBER OF SOURCE DOCUMENTS

43

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

This classification is based on the Bandolier system (http://www.jr2.ox.ac.uk/bandoiler/band6/b6-5.html) adapted for a systematic review.

Type & Strength of Evidence in Medical Literature

Type I: Evidence from a systematic review (which includes at least one randomized controlled trial and a summary of all included studies).

Type II: Evidence from a well designed randomized controlled trial of appropriate size.

Type III: Evidence from a well designed intervention study without randomization. A common research design is the before-and-after study.

Type IV: Evidence from a well designed non-experimental study, e.g., cohort, case-control or cross-sectional studies. (Also includes studies using purely qualitative methods. Economic analyses [cost-effectiveness studies] are also classified as Type IV evidence.)

Type V: Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert consensus committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations were a synthesis of research obtained in the evidence gathering process by a core group of two members. The recommendations were mailed to all committee members and feedback was obtained through a survey asking for comments and whether the recommendation should serve as a practice guideline. No significant disagreements existed.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The final statement incorporates all relevant evidence obtained by the literature search in conjunction with the final consensus recommendations supported by all working group members. The guideline was approved by the IRSA (International RadioSurgery Association) Board of Directors and issued in September 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Stereotactic radiosurgery is defined as a relatively high dose of focused radiation delivered precisely to the trigeminal root nerve, under the direct supervision of a medical team (neurosurgeon, radiation oncologist, registered nurse, and medical physicist), in one surgical session.
- Patients with typical trigeminal neuralgia who have had an adequate trial of medications can be offered stereotactic radiosurgery. Stereotactic radiosurgery is typically used in patients with medical co-morbidities or pain refractory to prior surgical procedures, patients at risk for side effects from percutaneous ablative procedures, and those in more advanced age groups.
- The optimal dose range for trigeminal neuralgia has been established. A commonly used dose range of 75 to 90 Gy in a single fraction to the trigeminal nerve is suggested, using a 4-mm collimator radiation field. Most

centers prefer 80 Gy as a central dose targeted to the trigeminal nerve a few millimeters proximal to its entry into the brain stem; however, 90 Gy as a central dose to the trigeminal nerve near the trigeminal ganglion has also been used routinely in some centers.

- Patients who have failed other surgical procedures for trigeminal neuralgia should also receive 75 to 90 Gy to the trigeminal nerve. A safe interval between the initial surgery and stereotactic radiosurgery is unknown, but it is reasonable to perform radiosurgery if there is no improvement or pain recurs following the initial surgical procedures.
- After radiosurgery, patients are followed to assess pain relief at three-month, six-month and yearly intervals. Their pre-radiosurgery pain medications are continued at the same doses until pain relief is obtained. Medications can be gradually tapered off if the patient remains pain free.
- Patients who have recurrence of pain following trigeminal neuralgia radiosurgery or who had a partial initial response can undergo a second stereotactic radiosurgery using 50 to 70 Gy to the trigerminal nerve (depending on the elapsed time between treatments). A generally safe interval between first and second radiosurgeries is six months.
- At present, technology to deliver focal small-volume fields is limited to Gamma Knife® by the strength of published data. Early data from dedicated modified linear accelerator centers with documented ability to deliver beams <5 mm are under evaluation.

CLINICAL ALGORITHM(S)

The original guideline contains a clinical algorithm for "Trigeminal Neuralgia Management."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Type I, II, and III evidence exists in support of stereotactic radiosurgery for intractable trigeminal neuralgia. Refer to the "Rating Scheme for the Strength of the Evidence" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Studies show a significant decrease in pain (decreased severity and reduced need to take medications). Complete pain relief (excellent or good) was maintained in 63.6 $\pm$ 3.3% of patients at one year and in 56.6 $\pm$ 3.8% at three years. Greater than 50% pain relief was maintained in 75.8 $\pm$ 2.9% of patients at one year and in 67.2 $\pm$ 3.9% at three years.
- Literature has documented the cost savings benefit of stereotactic radiosurgery versus invasive surgical procedures and the lower risk potential of bleeding, anesthesia problems, infections, and side effects which may be transient or permanent disabilities from open surgery.

POTENTIAL HARMS

The main complications after radiosurgery are new facial sensory symptoms caused by partial trigeminal nerve injury. Seventeen patients (7.7%) in one series developed increased facial paresthesia and/or facial numbness that lasted longer than six months. One patient (0.4%) developed deafferentation pain. Increased risk of trigeminal nerve dysfunction has been reported with the use of high-dose (90 Gy) radiosurgery.

CONTRAINDICATIONS

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Patients with well controlled trigeminal neuralgia through medical management

QUALIFYING STATEMENTS

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This guideline is not intended as a substitute for professional medical advice and does not address specific treatments or conditions for any patient. Those consulting this guideline are to seek qualified consultation utilizing information specific to their medical situation. Further, the IRSA does not warrant any instrument or equipment nor make any representations concerning its fitness for use in any particular instance nor any other warranties whatsoever.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

IRSA. Stereotactic radiosurgery for patients with intractable typical trigeminal neuralgia who have failed medical management. Harrisburg (PA): IRSA; 2003 Sep. 10 p. (Radiosurgery practice guideline report; no. 1-03). [43 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Sep

GUIDELINE DEVELOPER(S)

IRSA - Professional Association

GUIDELINE DEVELOPER COMMENT

IRSA is a non-profit entity dedicated to promoting the development of scientifically relevant practice guidelines for stereotactic radiosurgery. IRSA works to educate and provide support for physicians, hospitals, insurers, and patients.

SOURCE(S) OF FUNDING

IRSA

GUIDELINE COMMITTEE

IRSA Physician Advisory Board Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee members: Dr. L. Dade Lunsford, MD, Neurosurgeon (Chair); Ajay Niranjan, MBBS, MCh, Neurosurgeon; Ron Young, MD, Neurosurgeon; Ronald Brisman, MD, Neurosurgeon; David Cunningham, MD, Neurosurgeon; Christer Lindquist, MD, Neurosurgeon (European Co-Chair); David Newell, MD, Neurosurgeon; John C. Flickinger, MD, Radiation Oncologist; Ann Maitz, MS, Medical Physicist; Tonya K. Ledbetter, MS, MFS, Editor; Rebecca L. Emerick, MS, MBA, CPA, ex officio

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the IRSA Web site.

Print copies: Available from the IRSA, 3005 Hoffman Street, Harrisburg, PA 17110.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following are available:

- Trigeminal neuralgia & gamma knife® neurosurgery. Harrisburg (PA): IRSA. 2003.
- Trigeminal neuralgia. Brain Talk 2003;8(1):1-12. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.
- Trigeminal neuralgia. Another Perspective 1999 Fall;4(3):1-13. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.
- Neurosurgical radiosurgery. Brain Talk 2001;6(1):1-12. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.
- Radiosurgery & radiation therapy overview. Another Perspective 1999;4(2):1-12. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.

Print copies: Available from the IRSA, 3005 Hoffman Street, Harrisburg, PA 17110.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on March 8, 2004. The information was verified by the guideline developer on April 7, 2004.

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